WHAT IS CLAIMED IS:

1. A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to ~~or analogous to~~ the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

2. The method of claim 1, wherein the first sbp member is analogous to the analyte.

3. The method of claim 1, wherein the first sbp member is complementary to the analyte.

4. The method of claim 1, wherein the labeled first sbp member is an antiligand capable of binding the analyte.

5. The method of claim 1, wherein the first sbp member includes a visually detectable label.

6. The method of claim 5, wherein the visually detectable label comprises a visible particulate label.

7. The method of claim 1, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

8. The method of claim 1, wherein the second spb member is a ligand capable of binding the analyte.

9. The method of claim 1, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

10. The method of claim 1, wherein the second sbp member is an antibody against a complex formed between the analyte and the first sbp member.

11. The method of claim 1, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

12. The method of claim 9, wherein the ligand is a hapten and the receptor is a complement to the hapten.

13. The method of claim 1, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

14. The method of claim 1, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

15. The method of claim 1, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

16. A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of labeled first sbp member that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

17. The method of claim 16, wherein the labelled first spb member is a antibody capable of binding the analyte.

18. The method of claim 16, wherein the labelled first sbp member includes a visually detectable label.

19. The method of claim 18, wherein the visually detectable label comprises a visible particulate label.

20. The method of claim 16, wherein the second sbp member is attached to particles and the particles are immobilized in the one or more capture zones.

21. The method of claim 18, wherein the lateral flow matrix comprises a plurality of capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

22. The method of claim 18, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

23. The method of claim 18, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

24. A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, a barrier zone and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, the barrier zone comprises a second sbp member analogous to the analyte immobilized in the barrier zone, and each of the one or more capture zones comprises at least a third sbp member immobilized in the one or more capture zones, the third sbp member being capable of binding the first sbp member;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

25. The method of claim 26, wherein the labelled first spb member is an antibody capable of binding the analyte.

26. The method of claim 26, wherein the first sbp member includes a visually detectable label.

27. The method of claim 28, wherein the visually detectable label comprises a visible particulate label.

28. The method of claim 26, wherein the third sbp member is analogous to the analyte.

29. The method of claim 26, wherein the third sbp member is an antibody to the first sbp member.

30. The method of claim 26, wherein the third sbp member is attached to particles and the particles are immobilized in the capture zones.

31. The method of claim 26, wherein the lateral flow matrix comprises a plurality of capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

32. The method of claim 26, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

33. The method of claim 26, wherein the barrier zone comprises an amount of the second sbp member sufficient to bind substantially all of the labelled first sbp member when the analyte is present at a concentration below a predetermined threshold concentration.

34. The method of claim 26, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

35. A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, a barrier zone and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first specific binding pair member that is analogous to the analyte, the barrier zone comprises a second specific binding pair member that is complementary to the analyte, and each of the one or more capture zones comprises at least a third specific binding pair member immobilized in the one or more capture zones, the third specific binding pair member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

36. The method of claim 37, wherein the first sbp member includes a visually detectable label.

37. The method of claim 38, wherein the visually detectable label comprises a visible particulate label.

38. The method of claim 37, wherein the third sbp is an antibody to the analyte.

39. The method of claim 37, wherein the third sbp member is attached to particles and the particles are immobilized in the capture zones.

40. The method of claim 37, wherein the lateral flow matrix comprises a plurality of capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

41. The method of claim 37, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

42. The method of claim 37, wherein the second sbp member is present within the barrier zone in an amount sufficient to bind a threshold amount of the analyte.

43. The method of claim 37, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

44. A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone and at least first and second serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte whereby the first spb member and the analyte form an analyte-first spb member complex, the first capture zone comprises a second sbp member immobilized therein which is capable of binding the analyte-first sbp member complex with a first affinity, and the second capture zone comprises a third sbp member that is capable of binding the analyte-first spb member complex with a second affinity, the second affinity being different from the first affinity;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

45. The method of claim 46, wherein the labeled first sbp member is an antibody capable of binding the analyte.

46. The method of claim 46, wherein the first sbp member includes a visually detectable label.

47. The method of claim 48, wherein the visually detectable label comprises a visible particulate label.

48. The method of claim 46, wherein at least one of the second and third sbp members is an antibody to the analyte.

49. The method of claim 46, wherein at least one of the second and third sbp members is capable of binding the first sbp member.

50. The method of claim 46, wherein at least one of the second and third sbp members is an antibody to the first sbp member.

51. The method of claim 46, wherein the lateral flow matrix comprises a barrier zone between the labeling zone and the one or more capture zones, the barrier zone comprising a fourth sbp member immobilized thereon, the fourth sbp member being analogous to the analyte.

52. The method of claim 46, wherein the sample receiving zone comprises an amount of a fourth sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

53. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to ~~or analogous to~~ the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte.

54. The device of claim 55, wherein the first sbp member is analogous to the analyte.

55. The device of claim 55, wherein the first sbp member is complementary to the analyte.

56. The device of claim ~~55~~ 53, wherein the labeled first sbp member is an antibody capable of binding the analyte.

57. The device of claim 53, wherein the first sbp member includes a visually detectable label.

58. The device of claim 57, wherein the visually detectable label comprises a visible particulate label.

59. The device of claim 53, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

60. The device of claim 53, wherein the second spb member is an antibody capable of binding the analyte.

61. The device of claim 53, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

62. The device of claim 55, wherein the second sbp member is an antibody against a complex formed between the analyte and the first sbp member.

63. The device of claim 53, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

64. The device of claim 63, wherein the ligand is a hapten and the receptor is a complement to the hapten.

65. The device of claim 53, wherein the analyte is human IgE.

66. The device of claim 65, wherein the first sbp member is goat anti-human IgE and the second sbp member is mouse monoclonal anti-human IgE.

67. The device of claim ~~55~~ 53, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

68. The device of claim ~~55~~ 53, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

69. The device of claim 55, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

70. The device of claim ~~55~~ 53, wherein the device comprises a plurality of discrete lateral flow matrices.

71. The device of claim ~~72~~ 70, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

72. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte.

73. The device of claim ~~74~~ 72, wherein the labelled first spb member is an antibody capable of binding the analyte.

74. The device of claim ~~74~~ 72, wherein the labelled first sbp member includes a visually detectable label.

75. The device of claim ~~76~~ 74, wherein the visually detectable label comprises a visible particulate label.

76. The device of claim ~~74~~ 72, wherein the second sbp member is attached to particles and the particles are immobilized in the one or more capture zones.

77. The device of claim ~~74~~ 72, wherein the lateral flow matrix comprises a plurality of capture zones.

78. The device of claim ~~74~~ 72, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

79. The device of claim 74, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

80. The device of claim ~~74~~ 72, wherein the device comprises a plurality of discrete lateral flow matrices.

81. The device of claim ~~82~~ 80, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

82. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone;
a barrier zone; and
one or more serially oriented capture zones;
wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, the barrier zone comprises a second sbp member analogous to the analyte immobilized in the barrier zone, and each of the one or more capture zones comprises at least a third sbp member immobilized in the one or more capture zones, the third sbp member being capable of binding the first sbp member.

83. The device of claim 84, wherein the labelled first sbp member is an antibody capable of binding the analyte.

84. The device of claim 84, wherein the first sbp member includes a visually detectable label.

85. The device of claim 86, wherein the visually detectable label comprises a visible particulate label.

86. The device of claim 84, wherein the third sbp member is analogous to the analyte.

87. The device of claim 84, wherein the third sbp member is an antibody to the first sbp member.

88. The device of claim 84, wherein the third sbp member is attached to particles and the particles are immobilized in the capture zones.

89. The device of claim 84, wherein the lateral flow matrix comprises a plurality of capture zones.

90. The device of claim 84, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

91. The device of claim 84, wherein the barrier zone comprises an amount of the second sbp member sufficient to bind substantially all of the labelled first sbp member when the analyte is present at a concentration below a predetermined threshold concentration.

92. The device of claim 84, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

93. The device of claim 84, wherein the device comprises a plurality of discrete lateral flow matrices.

94. The device of claim 95, wherein the barrier zone in each of said plurality of discrete lateral flow matrices comprises a different amount of the second sbp member, sufficient to bind a different amount of the labeled first sbp member.

95. The device of claim 95, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

96. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;
a labeling zone;
a barrier zone; and
one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first specific binding pair member that is analogous to the analyte, the barrier zone comprises a second specific

binding pair member that is complementary to the analyte, and each of the one or more capture zones comprises at least a third specific binding pair member immobilized in the one or more capture zones, the third specific binding pair member being complementary to the analyte.

97. The device of claim 98, wherein the first sbp member includes a visually detectable label.

98. The device of claim 99, wherein the visually detectable label comprises a visible particulate label.

99. The device of claim 98, wherein the third sbp is an antibody to the analyte.

100. The device of claim 98, wherein the third sbp member is attached to particles and the particles are immobilized in the capture zones.

101. The device of claim 98, wherein the lateral flow matrix comprises a plurality of capture zones.

102. The device of claim 98, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

103. The device of claim 98, wherein the second sbp member is present within the barrier zone in an amount sufficient to bind a threshold amount of the analyte.

104. The device of claim 98, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

105. The device of claim 98, wherein the device comprises a plurality of discrete lateral flow matrices.

106. The device of claim 107, wherein the barrier zone in each of said plurality of discrete lateral flow matrices comprises a different amount of the second sbp member, sufficient to bind a different amount of the analyte.

107. The device of claim 107, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

108. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

at least first and second serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte whereby the first spb member and the analyte form an analyte-first spb member complex, the first capture zone comprises a second sbp member immobilized therein which is capable of binding the analyte-first sbp member complex with a first affinity, and the second capture zone comprises a third sbp member that is capable of binding the analyte-first spb member complex with a second affinity, the second affinity being different from the first affinity.

109. The device of claim 110, wherein the labeled first sbp member is an antibody capable of binding the analyte.

110. The device of claim 110, wherein the first sbp member includes a visually detectable label.

111. The device of claim 112, wherein the visually detectable label comprises a visible particulate label.

112. The device of claim 110, wherein at least one of the second and third sbp members is an antibody to the analyte.

113. The device of claim 110, wherein at least one of the second and third sbp members is capable of binding the first sbp member.

114. The device of claim 110, wherein at least one of the second and third sbp members is an antibody to the first sbp member.

115. The device of claim 110, wherein the lateral flow matrix comprises a barrier zone between the labeling zone and the one or more capture zones, the barrier zone comprising a fourth sbp member immobilized thereon, the fourth sbp member being analogous to the analyte.

116. The device of claim 110, wherein the sample receiving zone comprises an amount of a fourth sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

117. The device of claim 110, wherein the device comprises a plurality of discrete lateral flow matrices.

118. The device of claim 119, wherein the barrier zone in each of said plurality of discrete lateral flow matrices comprises a different amount of the second sbp member, sufficient to bind a different amount of the analyte.

119. The device of claim 119, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

120. A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of any one of claims 55, 74, 84, 98 or 110, a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

sub a7

add a8